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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,908	07/25/2007	Sylvie Tournade	3712036.00755	1892
29157	7590	10/28/2010	EXAMINER	
K&L Gates LLP			ARIANI, KADE	
P.O. Box 1135				
CHICAGO, IL 60690				
			ART UNIT	PAPER NUMBER
			1651	
			NOTIFICATION DATE	DELIVERY MODE
			10/28/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,908	<b>Applicant(s)</b> TOURNADE ET AL.	
	<b>Examiner</b> KADE ARIANI	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 8-11, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***DETAILED ACTION***

The amendment filed on August 17, 2010, has been received and entered.

Claim 12 has been cancelled.

Claims 1-10, 13, and 14 are pending in this application, claims 8-11, 13, and 14 are withdrawn from consideration, and claims 1-7 are examined on their merits.

Applicant's arguments with respect to claims 1-7 filed on 08/17/2010 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Objection***

The objection to claims 1, 3, 4, and 6 are withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.

Claim 12 is cancelled therefore the rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly define the metes and bounds of the subject matter which applicant regards as the invention, is withdrawn.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 reads "a liquid product which is water-based and comprises living microorganisms,,, and which is free of carbohydrates that can be metabolized by the microorganisms". This is vague and indefinite because it is not clear what "microorganisms" and what "carbohydrates" are being claimed and the boundaries of the patent protection sought is not clear. Therefore claim 1 fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-4, 6, 7 under 35 U.S.C. 102(b) as being anticipated by Reniero et al. (WO 00/53202), is withdrawn.

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1-7 and 12 under 35 U.S.C. 103(a) as being unpatentable over Reniero et al. (WO 00/53202) in view of Kailasapathy K. (Current Issue Intest. Microbiol., 2002, Vol.3, p.39-48) and further in view of Hottinger et al. (US Patent No. 5,382,438), is withdrawn.

Claims 1-4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reniero et al. (WO 00/53202) in view of Schlothauer et al. (US Patent No. 7,780,970 B2).

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Claims 1-4, 6, and 7 are drawn to a liquid product which is water-based and comprises living microorganisms, having a shelf-life of at least 1 month at 10°C, and during the 1 month at 10°C the amount of living bacteria decreases less than 2 log-units, which is free of carbohydrates that can be metabolized by the microorganisms, the product comprising milk proteins, the microorganisms do not metabolize lactose, microorganisms are from genus *Lactobacillus*, the microorganisms are probiotics, the pH of the product at the beginning of storage is 4 or higher.

Reniero et al. teach a liquid product which is water-based and comprises living microorganisms, having a shelf-life of at least 1 month at 10°C, and during the 1 month at 10°C period the amount of living bacteria decreases less than 2 log-units, the microorganism is a *Lactobacillus* (a cereal drink comprising *L. casei* CNM I-2116 or ST11 which is stored at 10°C for 30 days, and the survival rate after 30 days less than 2 log units) (page 29 of the "PDF" Figure 3., viable cell count for the 1<sup>st</sup> curve form the top highest count about 9.2 log cfu/ml and lowest about between 8.8 and 9.0, and p.5 Fig.3. description). Reniero et al. also teach the pH of at the beginning of storage at 10°C is 4 or higher (pH of 4.4) (p.17 Example 8. 2<sup>nd</sup> paragraph). Reniero et al. teach a microorganism *L. casei* CNM I-2116, (p.23 claim 6). It must be noted that microorganism *L. casei* CNM I-2116 or ST11 does not use (metabolize) lactose. Reniero et al. further teach milk (milk proteins) can be used (p. 24 claim 14), and the microorganisms are probiotics (p.2 2<sup>nd</sup> paragraph lines 1-2).

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Reniero et al. do not teach the liquid product (cereal drink) is free of carbohydrates that can be metabolized by the *Lactobacillus*. However, Reniero et al. teach *L. casei* CNNM I-21 is capable of utilizing carbohydrates sucrose and glucose and, also teach acidification of the medium after supplementing the growth medium of *L. casei* CNNM I-2116, with sucrose and glucose (please note that the pH of the medium drops from 6.50 to 5.50 and continues to drop to pH 4.0 when sucrose and glucose are included in the growth medium) (see page 28 of the PDF Figure 2. acidification of *L. casei* ST11 or CNNM I-2116, pH vs. fermentation time in hours). Therefore, a person of ordinary skill in the art at the time the invention was made would have recognized that the *Lactobacillus* taught by Reniero et al. was capable of utilizing carbohydrates sucrose and glucose, and a person of ordinary skill in the art would have recognized that the presence of carbohydrates sucrose and glucose in liquid medium of *L. casei* ST11 would have increased the rate of acidification (drop in pH) of the medium.

Further motivation not to include the carbohydrates that can be metabolized by the microorganism is in Schlothauer et al. who teach sucrose free products would have a reduced detrimental effect on the teeth (column 11 lines 29-30).

Therefore, a person of ordinary skill in the art at the time the invention was made, recognizing that the presence of carbohydrates that can be metabolized by the microorganism in the liquid product would have increased the rate of acidification of the product, would have been motivated to apply the prior art teachings and not to include the carbohydrates that can be metabolized by the microorganism in the liquid product as taught by Reniero et al. in order to provide a liquid product which is water-based and

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comprises *Lactobacillus*, having a shelf-life of at least 1 month at 10°C, and during the 1 month at 10°C the amount of living bacteria decreases less than 2 log-units, which is free of carbohydrates that can be metabolized by the microorganisms. Because Reniero et al. teach the presence of carbohydrates (sucrose and glucose) that can be utilized by the *Lactobacillus*, *L. casei* CNNM I-21 increases the acidification (drop in pH) of the medium, and because Schlothauer et al. teach sucrose free products would have a reduced detrimental effect on the teeth.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reniero et al. (WO 00/53202) in view of Kailasapathy K. (Current Issue Intest. Microbiol., 2002, Vol.3, p.39-48) and further in view of Hottinger et al. (US Patent No. 5,382,438).

As mentioned immediately above, Reniero et al. teach a liquid product which is water-based and comprises living microorganisms, having a shelf-life of at least 1 month at 10°C, and during the 1 month at 10°C period the amount of living bacteria decreases less than 2 log-units, the microorganism is a *Lactobacillus* (a cereal drink comprising *L. casei* CNNM I-2116 or ST11 which is stored at 10°C for 30 days, and the survival rate after 30 days less than 2 log units) (page 29 of the "PDF" Figure 3., viable cell count for the 1st curve form the top highest count about 9.2 log cfu/ml and lowest about between 8.8 and 9.0, and p.5 Fig.3. description). Reniero et al. also teach the pH of at the beginning of storage at 10°C is 4 or higher (pH of 4.4) (p.17 Example 8. 2nd paragraph). Reniero et al. teach a microorganism *L. casei* CNNM I-2116, (p.23 claim 6).



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It must be noted that microorganism *L. casei* CNNM I-2116 or ST11 does not use (metabolize) lactose. Reniero et al. further teach milk (milk proteins) can be used (p. 24 claim 14), and the microorganisms are probiotics (p.2 2nd paragraph lines 1-2). Reniero et al. teach *L. casei* CNNM I-21 is capable of utilizing carbohydrates sucrose and glucose and, also teach acidification of the medium after supplementing the growth medium of *L. casei* CNNM I-2116, with sucrose and glucose (please note that the pH of the medium drops from 6.50 to 5.50 and continues to drop to pH 4.0 when sucrose and glucose are included in the growth medium) (see page 28 of the PDF Figure 2. acidification of *L. casei* ST11 or CNNM I-2116, pH vs. fermentation time in hours). Therefore, a person of ordinary skill in the art at the time the invention was made would have recognized that the *Lactobacillus* taught by Reniero et al. was capable of utilizing carbohydrates sucrose and glucose, and a person of ordinary skill in the art would have recognized that the presence of carbohydrates sucrose and glucose in liquid medium of *L. casei* ST11 would have increased the rate of acidification (drop in pH) of the medium, and would have been motivated not to include the carbohydrates that can be metabolized by the microorganism in the liquid product as taught by Reniero et al. in order to minimize the acidification of the liquid product comprising the microorganism during storage. Also at the time the invention was made a person of ordinary skill in the art would have known that sucrose free products would have a reduced detrimental effect on the teeth and would have been motivated to provide a sucrose-free liquid product.

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Reniero et al. do not teach the product at 20°C experiences a decrease in pH of less than 2 points. However, Kailasapathy teaches probiotic microorganisms with extended shelf-life at room temperatures for formulating products (microencapsulated probiotic strains with extended shelf-life at room temperatures (about 20°C) (p.46 1<sup>st</sup> column 2<sup>nd</sup> paragraph lines 8-13). Kailasapathy also teaches microencapsulated probiotics have increased survival in acid fermented products (p.45 1<sup>st</sup> column 3<sup>rd</sup> paragraph lines 8-11).

Moreover, Hottinger et al. teach because of the symbiosis of microorganisms it is possible to keep a milk-based product (yogurt) even at ambient temperature without the pH falling by more than about 0.05 to 0.5 unit (column 4 lines 5-9). Hottinger et al. also teach the degree of post-acidification in a milk-based product (yogurt) is not affected by the presence of a carbohydrate (glucose) in the milk when the microorganism used is not able to metabolize the carbohydrate (column 8 lines 15-37).

Therefore, a person of ordinary skill in the art at the time the invention was made, would have been motivated to apply the prior art teachings and to use a probiotic strain with extended shelf life at room temperature (about 20°C) as taught by Kailasapathy in the liquid product of Reniero et al. with a reasonable expectation of success in providing a liquid product comprising probiotic microorganisms with extended shelf-life for 1 month at 20°C, because Kailasapathy teaches probiotic microorganisms with extended shelf-life at room temperatures (about 20°C) can be formulated into food products, and because Hottinger et al. teach due to the symbiosis of microorganisms in a milk-based

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product it is possible to keep the product even at ambient temperature without the pH falling by more than about 0.05 to 0.5 unit.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kade Ariani/  
Examiner, Art Unit 1651